

## **REMARKS**

### **The Rejection under 35 U.S.C. §112, first paragraph**

The rejection of claims 33, 38, 40, 42, 46-51, 53-55 and 57-63 under 35 U.S.C. §112, first paragraph, for lack of written description, is respectfully traversed.

It is alleged that the specification fails to provide a description of specific embodiments of the “drug that kills fat cells” as recited in the claims. However, it is not necessary for applicants to provide such a description because such compounds are known and one of ordinary skill in the art would be able to readily ascertain what compounds would provide this function. Further, the instant specification does provide representative examples of such compounds. The instant specification makes clear that such drugs were known and provides sources showing examples thereof, i.e., it is stated on page 2, second full paragraph: “It has been known that certain drugs, including TNF- $\alpha$ , can be generally administered, as opposed to locally administered, to combat obesity; see, e.g., Shah (U.S. Patent No. 6,020,004), Larrick et al. (U.S. Patent No. 4,684,623), Girtten et al. (U.S. Patent No. 5,726,156) and Cincotta et al. (U.S. Patent No. 5,344,832).” As the previous prosecution and the instant specification make clear, applicants’ invention does not lie in the specific nature of the drug but in the novel manner of administering such a drug. The nature of the invention is thus reasonably conveyed to one of ordinary skill in the art sufficient for written description purposes under 35 U.S.C. §112. The law is clear that “A patent need not teach, and preferably omits, what is well known in the art.” Spectra-Physics, Inc. v. Coherent, Inc., 827 F.2d 1524, 1534, 3 USPQ2d 1737, 1743 (Fed. Cir. 1987). Thus, the rejection under 35 U.S.C. §112, first paragraph, should be withdrawn.

### **The Rejection under 35 U.S.C. §112, second paragraph**

The rejection of claim 33 for indefiniteness under 35 U.S.C. §112, second paragraph, is respectfully traversed.

Applicants submit that the basis for rejections for indefiniteness under 35 U.S.C. §112, second paragraph, for terms “such as” or “preferably” are not applicable to the instant claims. No such terms reciting a narrow range together with a broad range appear in the instant claims. The recitation “a drug that kills fat cells; methotrexate; bromo-deoxyuridine; actinomycin D; nocodazole; brefeldin A; a beta-adrenergic stimulator; or, an alpha-2 adrenergic inhibitor” contains terms that define compounds, not ranges. Some of these terms define a broader aspect of compounds than others but this is common for patent claims and not indefinite or improper. As described above in connection with the traversal of the written description rejection, one of ordinary skill in the art is well aware of the meaning and metes and bounds of each of these terms. Thus, one of ordinary skill in the art can readily identify whether a compound falls within this definition of compounds used for the claimed invention or does not. Thus, there is no indefiniteness. The claim clearly conveys the metes and bounds of this claim term.

The MPEP §2173.05(c) specifically addresses the issue of narrow and broad ranges together. But it clearly is directed only to “numerical” ranges. The objected to recitation here has no relation to numerical ranges. To the contrary, MPEP §2713.05(o) does address the double inclusion situation where two claim terms may encompass the same compound, i.e., the alleged facts here. It states: “The mere fact that a compound may be embraced by more than one member of a Markush group recited in the claim does not lead to any uncertainty as to the scope of that claim for either examination or infringement purposes.” Thus, the MPEP is consistent with the applicants’ position stated above and contrary to the grounds of rejection.

For all of the above reasons, it is urged that the rejection under 35 U.S.C. §112, second paragraph, should be withdrawn.

### **The Rejection under 35 U.S.C. §103**

The rejection of claims 33, 36, 38, 40, 42 and 46-63 under 35 U.S.C. §103, as being obvious over Friedman (U.S. Patent No. 6,124,439), Greenway (U.S. Patent No. 4,588,724), Woiszwilllo (U.S. Patent No. 5,981,719) and Neville (U.S. Patent No. 5,066,490) in view of Acharya (U.S. Patent No. 5,686,094), Hubbell (U.S. Patent No. 6,129,761) and Shah (U.S. Patent No. 6,020,004), is respectfully traversed.

The statement of the rejection discusses what each of the references individually teaches and how each reference discloses some element which is allegedly part of the claimed invention. It also discusses why such features were found advantageous for each of the reference inventions. But the Office action provides no objective reasons why one of ordinary skill in the art would pick and choose amongst the various features of the prior art references only those specific parts which result in the claimed invention and combine them. In KSR International Co. v. Teleflex Inc., 550 U.S. \_\_\_, 82 USPQ2d 1385 (2007), the Supreme Court cited with approval In re Kahn, 441 F. 3d 977, 988 (Fed. Cir. 2006), stating: “[R]ejections on obviousness grounds cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness.” While the statement of the rejection articulates reasons why the references individually disclose certain elements and why one of ordinary skill in the art would be motivated to use those elements in those inventions, there is no articulated reasoning as to why one of ordinary skill in the art would combine these elements. The Office action merely concludes that one of ordinary skill in the art would have a reasonable expectation of success of carrying out the claimed invention in view of the reference

teachings and therefore it is obvious. But no reasons are given why this would be so. Further, no reasons are given for why one of ordinary skill in the art would make all the selections necessary from among the seven cited references and combine them in a way which results in the claimed invention. Merely because separate references teach the separate elements of the invention does not support obviousness of their combination. To the contrary, it is well settled that even if the elements of combination invention are known the combination may be patentable; see, e.g., Rosemount, Inc. v. Beckmann Instruments, Inc., 221 USPQ 1, 7 (Fed. Cir. 1984); and, Ryko Manufacturing Co. v. Nu-Star, Inc., 21 USPQ2d 1053 (Fed. Cir. 1991), stating, "For a combination or any other invention to have been obvious, the prior art must suggest the desirability of making the claimed invention."

Further, the fact that it was necessary to combine elements from seven different references to piece together the claimed invention makes it even more critical that articulated reasons be provided as to why one of ordinary skill in the art would select and combine the discrete elements of these references which were necessary to arrive at the claimed invention. Although it is true that a rejection is not improper merely because it relies on a large number of references, it is also true that the references cannot be viewed using applicant's own disclosure as a blueprint or guide to selectively pick discrete elements of the references and piece them together to arrive at the invention. See, e.g., Grain Processing v. American Maize, 5 USPQ2d 1788, 1792 (Fed. Cir. 1988); and Orthopedic Equipment Co., Inc. v. United States, 217 USPQ 193, 199 (Fed. Cir. 1983). Applicants can see no reason (and none is articulated in the Office action) to combine the teachings from the seven different references to arrive at the particular combination of the claimed invention, absent reliance on applicants' own disclosure. There are thousands of other possible combinations which could be arrived at from the references and no direction to applicants' particular combination is apparent.

For the above reasons, it is urged that the claimed invention is not rendered obvious from the cited prior art and the rejection under 35 U.S.C. §103 should be withdrawn. But further discussion of the specific references is provided below for completeness.

Friedman is directed to providing macromolecular nucleic acids or protein compounds connected with the OB gene for controlling body weight. Friedman is thus not directed to methods for controlling body weight using a substance wherein the “substance is a small molecule drug” as recited in the instant claims. To the contrary, providing a macromolecular polypeptide compound is the primary feature of the Friedman invention and replacing it with a small molecular would be directly contrary to the objectives of the reference. In such case, there would be no reason for one of ordinary skill in the art to make such a modification. Further, Friedman fails to suggest a method for “administering a controlled release formulation to the patient by injection into the adipose tissue at a local area such that undesired adipose tissue in the local area is selectively reduced.” Friedman generically lists “injection” broadly as one manner of administration but there is no indication of local administration by injection for a local effect. To the contrary, all the further discussion in Friedman, cols. 43-47, is directed to systemic administration methods for a general effect. No reason is provided to support why one of ordinary skill in the art would modify Friedman’s method to conduct local administration achieve or a local effect or use a controlled release carrier.

Greenway discloses the use of a beta-adrenergic stimulator or an alpha-2 adrenergic inhibitor to achieve regional weight reduction in humans. There is no objective reason for why one of ordinary skill in the art would use the Greenway compounds in the Friedman method. Further, Greenway also provides no suggestion of administering the compounds as a controlled release formulation in its method.

Woiszwillo is directed to microparticles of a macromolecule mixed with a polymer.

Applicants see no relation of this to the claimed invention. The claimed method relates to administering a substance in a particular defined way for a particular defined effect where the “substance is a small molecule drug,” not a macromolecule. While the controlled release carrier can be a PEG-macromolecule, this is just the carrier and the active agent is the small molecule carried by it. Woiszwilllo discloses that its particles can be used to provide sustained release of a macromolecule, among a wide variety of other uses. However, it teaches nothing regarding controlled release of a small molecule or methods for administering such a small molecule controlled release formulation by injection into the adipose tissue at a local area such that undesired adipose tissue in the local area is selectively reduced.

Neville, similar to Woiszwilllo, is directed to carrier materials for macromolecules, such as proteins or enzymes. Neville discusses as part of the prior art (col. 4, lines 9-22) that PEG-conjugated proteins had been used to deliver enzyme proteins. However, this again relates to carriers for macromolecules, not small molecules. Further, Neville indicates that these materials have problems in relation to its materials. Finally, like Woiszwilllo, Neville provides no suggestion that its materials would be useful in a method for administering a small molecule controlled release formulation by injection into the adipose tissue at a local area such that undesired adipose tissue in the local area is selectively reduced.

Acharya is directed to a very specific polymer carrier system designed for a very specific uses. The carrier is of calcium polycarbophil. The uses are described at cols. 3 and 4 but include no hint of methods for administering a small molecule controlled release formulation by injection into the adipose tissue at a local area such that undesired adipose tissue in the local area is selectively reduced.

Hubell is directed to a carrier for injecting isolated cells. It has no relation to a formulation for controlled release of a small molecule drug. Further, it has no relation to a

method for administering such a small molecule controlled release formulation by injection into the adipose tissue at a local area such that undesired adipose tissue in the local area is selectively reduced. No connection to the claimed invention is apparent.

Shah is similar to Neville and Woiszwilllo. Shah is primarily directed to polymeric microparticles useful as carriers for macromolecules, particularly therapeutic proteins; see, e.g., col. 1, lines 13-27. Shah does generally discuss a broader applicability, including for small molecules, e.g., col. 4, lines 51-65. But the reference provides no suggestion that its materials would be useful in a method for administering a small molecule controlled release formulation by injection into the adipose tissue at a local area such that undesired adipose tissue in the local area is selectively reduced. Shah's disclosure as a whole makes clear that it is primarily directed to providing carriers for proteins. Thus, applicants see no reason why one of ordinary skill in the art would have reason to use Shah's carrier for a method using a small molecule which is administered in a very specific way for a very specific purpose, neither of which have any mention by Shah.

For all of the above reasons, it is urged that the references considered as a whole do not suggest the claimed invention to one of ordinary skill in the art. As discussed above, there is no reason set forth or apparent on the record why one of ordinary skill in the art would combine the various reference teachings in a manner which suggests the claimed invention. Thus, the claimed invention is not rendered obvious under 35 U.S.C. §103 and the rejection should be withdrawn.

It is submitted that the claims are in condition for allowance. However, the Examiner is kindly invited to contact the undersigned to discuss any unresolved matters.

No fee is believed to be due with this Amendment. However, the Commissioner is hereby authorized to charge any additional fees associated with this response or credit any overpayment to Deposit Account No. 13-3402.

Respectfully submitted,

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